

71531 U.S. PTO
05/06/97

A/NO FEB

PATENT
Atty. Docket No. CRP-145

74280 U.S. PTO
08851628
05/06/97

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of
Inventor(s): Kuber T. Sampath and Charles M. Cohen

WARNING: Patent must be applied for in the name(s) of all of the actual inventor(s). 37 CFR 1.41(a) and 1.53(b)

For (title): NOVEL THERAPIES FOR CHRONIC RENAL FAILURE

1. Type of Application

This new application is for a(n) (check one applicable item below):

- ☒ Original
☐ Design
☐ Plant

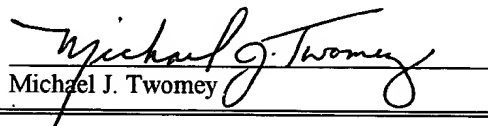
WARNING: Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. 371(c)(4) unless the International Application is being filed as a divisional, continuation or continuation-in-part application.

NOTE: If one of the following 3 items apply then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED.

- ☐ Divisional
☐ Continuation
☐ Continuation-in-Part

CERTIFICATE OF EXPRESS MAILING UNDER 37 C.F.R. 1.10

I hereby certify that the attached document is being deposited with the United States Postal Service, postage prepaid, on May 6, 1997 utilizing the "Express Mail Post Office to Addressee" service of the United States Postal Service, mailing label number EM354713201US, in an envelope addressed to the Assistant Commissioner for Patents, Washington, DC 20231.


Michael J. Twomey

2. Benefit of Prior U.S. Application(s) (35 USC 120)

NOTE: If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., then check either the first option below or the second option below. If the second option is checked, the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION (S) IS CLAIMED must be completed and attached.

- ☐ The new application transmitted claims the benefit of prior U.S. application(s) and the priority information is contained in the enclosed new application
- ☐ The new application being transmitted claims the benefit of prior U.S. application(s) and enclosed are ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

3. Papers Enclosed Which Are Required For Filing Date Under
37 CFR 1.53(b) (Regular) or 37 CFR 1.153 (Design) Application

33 Pages of specification
7 Pages of claims
1 Pages of Abstract
6 Sheets of drawing

- ☐ formal
- ☒ informal

WARNING: DO NOT submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to § 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. **Only one copy is required or desired.** Comments on proposed new 37 CFR 1.84. Notice of March 9, 1988 (1990 O.G. 57-62).

NOTE: "Identifying indicia such as the serial number, group and unit, title of the invention, attorney's docket number, inventor's name, number of sheets, etc., not to exceed 2-3/4 inches (7.0 cm.) in width may be placed in a centered location between the side edges within three fourths inch (19.1 mm.) of the top edge. Either this marking technique on the front of the drawing or the placement, although not preferred, of this information and the title of the invention on the back of the drawings is acceptable." Proposed 37 CFR 1.84(1). Notice of March 9, 1988 (1090 O.G. 67-62).

4. Additional papers enclosed

- ☐ Preliminary Amendment
- ☐ Information Disclosure Statement
- ☐ Form PTO-1449
- ☐ Citations
- ☐ Declaration of Biological Deposit

- ☐ Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.
- ☐ Authorization of Attorney(s) to Accept and Follow Instructions from Representative
- ☐ Special Comments
- ☐ Other

5. Declaration or oath

- ☒ Enclosed but unexecuted.
- ☐ Enclosed
executed by (check all applicable boxes)
 - ☐ inventor(s).
 - ☐ legal representative of inventor(s). 37 CFR 1.42 or 1.43
 - ☐ joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.
 - ☐ this is the petition required by 37 CFR 1.47 and the statement required by 37 CFR 1.47 is also attached.
See item 13 below for fee.
- ☐ Not Enclosed.

WARNING:

Where the filing is a completion in the U.S. of an International Application but where a declaration is not available or where the completion of the U.S. application contains subject matter in addition to the International Application the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.

- ☐ Application is made by a person authorized under 37 CFR 1.41(c) on behalf of all the above named inventor(s). The declaration or oath, along with the surcharge required by 37 CFR 1.16(e) can be filed subsequently.

NOTE: It is important that all the correct inventor(s) are named for filing under 37 CFR 1.41(c) and 1.53(b).

- ☐ Showing that the filing is authorized.
(Not required unless called into question. 37 CFR 1.41(d).)

6. Inventorship Statement

WARNING: If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.

The inventorship for all the claims in this application are:

- ☒ The same
- ☐ ~~Are not the same. An explanation, including the ownership of the various claims~~
at the time the last claimed invention was made,
- ☐ is submitted.
- ☐ will be submitted.

7. Language

NOTE: An application including a signed oath or declaration may be filed in a language other than English. A verified English translation of the non-English language application and the processing fee of \$130.00 required by 37 CFR 1.17(k) is required to be filed with the application or within such time as may be set by the Office. 37 CFR 1.52(d).

NOTE: A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 CFR 1.69(b).

- ☒ English
- ☐ non-English
- ☐ the attached translation is a verified translation. 37 CFR 1.52(d).

8. Assignment

- ☐ An assignment of the invention to
- ☐ is (are) attached. A separate "ASSIGNMENT COVER LETTER ACCOMPANYING NEW PATENT APPLICATION" is also attached.
- ☒ will follow.

NOTE: "If an assignment is submitted with a new application, send two separate letters -- one for the application and one for the assignment." Notice of May 4, 1990 (1114 D.G. 77-78).

9. **Certified Copy**
Certified copy(ies) of the application(s)

[illegible]

from which priority is claimed

☐ is (are) attached.

☐ will follow.

NOTE: The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 CFR 1.55(a) and 1.63.

NOTE: This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application from which this application claims benefit under 35 U.S.C. 120 is itself entitled to priority from a prior foreign application then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

10. Fee Calculation (37 CFR 1.16)

A. ☒ Regular application

CLAIMS AS FILED

	Number Filed	Number Extra		Rate	Basic Fee 37 CFR 1.16(a) \$770.00
Total Claims (37 CFR 1.16 (c))	51	- 20 = 31	X	\$ 22.00	\$
Independent Claims (37 CFR 1.16 (b))	2	- 3 =	X	\$ 80.00	\$
Multiple Dependent Claim(s), If any (37 CFR 1.16(d))			+	\$ 260.00	\$

☐ Amendment canceling extra claims enclosed.

☐ Amendment deleting multiple-dependencies enclosed.

☒ Fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims canceled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 CFR 1.16(d).

Filing Fee Calculation \$

B. ☐ Design application
(\$320.00--37 CFR 1.16(f))

Filing Fee Calculation \$

C. ☐ Plant application
(\$530.00--37 CFR 1.16(g))

Filing Fee Calculation \$

11. Small Entity Statement(s)

- ☐ Verified Statement(s) that this is a filing by a small entity under 37 CFR 1.9 and 1.27 is (are) attached.

Filing Fee Calculation (50% of A, B or C above) \$

NOTE: Any excess of the full fee paid will be refunded if a verified statement and a refund request are filed within 2 months of the date of timely payment of a full fee. 37 CFR 1.28(a).

12. Request for International-Type Search (37 CFR 1.104(d)) (complete, if applicable)

- ☐ Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

13. Fee Payment Being Made At This Time

- ☒ Not Enclosed
- ☒ No filing fee is to be paid at this time. (This and the surcharge required by 37 CFR 1.16(e) can be paid subsequently.)
- ☐ Enclosed
- | | |
|---|----|
| <input type="checkbox"/> basic filing fee | \$ |
| <input type="checkbox"/> recording assignment
(\$40.00; 37 CFR 1.21(h)) | \$ |
| <input type="checkbox"/> petition fee for filing by other than all the
inventors or person on behalf of the
inventor where inventor refused to sign
or cannot be reached.
(\$130.00; 37 CFR 1.47 and 1.17(h)) | \$ |
| <input type="checkbox"/> for processing an application with a
specification in a non-English language.
(\$130.00; 37 CFR 1.52(d) and 1.17(k)) | \$ |
| <input type="checkbox"/> processing and retention fee (\$130.00;
37 CFR 1.53(d) and 1.21 (1). | \$ |
| <input type="checkbox"/> fee for international-type search report
(\$40.00; 37 CFR 1.21 (e)). | \$ |

NOTE: 37 CFR 1.21(l) establishes a fee for processing and retaining any application which is abandoned for failing to complete the application pursuant to 37 CFR 1.53(d) and this, as well as the changes to 37 CFR 1.53 and 1.78, indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing

fee must be paid or the processing and retention fee of § 1.21(l) must be paid within 1 year from notification under § 53(d).

Total fees enclosed \$ 0.00

14. Method of Payment of Fees

- ☐ Check in the amount of \$
- ☐ Charge Account No.20-0531 in the amount of \$_____. A duplicate of this transmittal is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 CFR 1.22(b).

15. Authorization to Charge Additional Fees

WARNING: If no fees are to be paid on filing the following items should not be completed.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.

- ☐ The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. 20-0531.

- ☐ 37 CFR 1.16(a),(f) or (g) (filing fees)
- ☐ 37 CFR 1.16(b),(c) and (d)(presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims canceled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

- ☐ 37 CFR 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)
- ☐ 37 CFR 1.17 (application processing fees)

WARNING: While 37 CFR 1.17(a),(b), (c) and (d) deal with extensions of time under § 1.136(a) this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 C.F.R. 1.136(a) is to no avail unless a request or petition for extension is filed." (Emphasis added). Notice of November 5, 1985 (1060 O.G. 27).

- ☐ 37 CFR 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 CFR 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance, 37 CFR 1.31(b).

NOTE: 37 CFR 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying, . . . issue fee". From the

wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

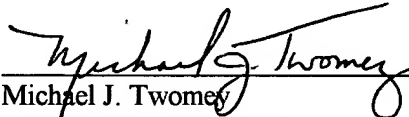
16. Instructions As To Overpayment

- ☐ credit Account No. 20-0531
- ☐ refund

Date: May 6, 1997

Reg. No. 38,349

Tel. No. (617) 248-7362



Michael J. Twomey
Attorney for Applicant(s)
Testa, Hurwitz, & Thibault, LLP
High Street Tower
125 High Street
Boston, Massachusetts 02110

☐ Incorporation by reference of added pages

Check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED

☐ Plus Added Pages For New Application Transmittal Where Benefit of prior U.S. Application(s) Claimed

Number of pages added

☐ Plus Added Pages For Papers Referred To In Item 4 Above

Number of pages added

☐ Plus "Assignment Cover Letter Accompanying New Application"

Number of pages added

☐ Statement Where No Further Pages Added

(if no further pages form a part of this Transmittal then end this Transmittal with this page and check the following item)

☒ This transmittal ends with this page.

395MJT2054/18/356853-1